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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,402	09/12/2003	Andrew Vaillant	16051-7US CC	6670

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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,402	VAILLANT ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *1-51 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *Nov. 26, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 52-56 in the reply filed on December 16, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).

Claims 1-51 and 57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 16, 2005.

Claims 52-56 are examined in the instant application. There was no species requirement for the elected Group I, however the applicant made an election of a single stranded DNA having 40 wobbles (REP 2006) at every position (40 nucleotides randomer oligonucleotide each linked by a phosphorothioate linkage). The species election is acknowledged but is not being considered for examination of claims 52-56.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 52-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 52, the phrase "different from" renders the claim indefinite because it is unclear whether the antiviral oligonucleotides include or exclude the viruses listed in claim 52. The claim language does not describe the metes and bounds of which viruses are included in the invention. The claim only describes what is not part of the claimed invention. See MPEP § 2173.05(d).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

M.P.E.P. § 2163 recites, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention... one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the

knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

The claims are broad as they read on a method of selecting an antiviral oligonucleotide for use as an anti-viral agent against a target virus. The specification does not describe how to select an antiviral oligonucleotide against each and every virus that can cause infection. This encompasses an astronomical number of sequences. The specification discloses examples with HSV-1, HSV-2, HIV, CMV, RSV, coxsackie B12, DHBV, parainfluenza 3 and Hanta virus, however, most of these viruses in the examples are excluded from the instant claims. This is not a representative number of species for the claimed invention because only a few virus families are represented. The specification would need to describe a representative oligonucleotide against many viral families. There is a plethora of viral familes and the oligonucleotides may or may not be effective against the specific viruses listed in claim 1.

Viruses have very divergent genomes and methods of propagating. Viruses within virus families differ in methods of replication, cell affinity and hosts. There is not sufficient evidence of possession of oligonucleotides having anti-viral activity against every virus in the claimed invention. An artisan would not be able to envision the claimed invention based on the information provided in the specification.

A representative number of species are disclosed by functional characteristics and structure but not all species are adequately described for representation of the entire genus of viral infections. A genus cannot be claimed after only describing a limited number of species because of the unpredictability in the results obtained from

other species. The instantly disclosed number of species is not representative of the claimed genus and is not satisfactory to show one of skill in the art to recognize that the applicant was in possession of the claimed invention.

Claims 52-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antiviral oligonucleotide against HIV, HSV, CMV and RSV, does not reasonably provide enablement for an antiviral oligonucleotide against every virus that causes infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the specific antiviral oligonucleotides the invention commensurate in scope with these claims. It is unclear if the antiviral oligonucleotides interact with only the target viruses or they can interact with any virus. The scope of the invention as claimed is the said oligonucleotide has activity exclusively with all viruses different from HIV, HSV, CMV, RSV, parainfluenza and HBV.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The breadth of the claim is unreasonable as it reads to any virus different from HIV, HSV, CMV, RSV, parainfluenza and HBV. The very broad claims are drawn to oligonucleotides which have activity with all viruses other than the viruses listed above.

These said oligonucleotides comprise different oligonucleotides wherein at least one oligonucleotides is at least 10 nucleotides in length.

The nature of the invention is drawn to antiviral oligonucleotides synthesized against viruses to inhibit virus production of infectious virions. The state of the prior art teaches antisense oligonucleotides synthesized to inhibit viral growth *in vitro*. T Abe, et al., teaches oligonucleotide synthesis to produce antiviral activity specifically against influenza virus (p. 254). One of ordinary skill in the art would be considered to have a high level of knowledge, possess a pHD, have many years of experience in the laboratory and authored several publications.

The level of predictability in the art is variable. Oligonucleotides and PCR products are not 100% predictable. There is not sufficient evidence that indicates an ordinary artisan could predict the operability in the invention of any species other than the ones disclosed in the specification. The amount of direction provided by the specification is not sufficient to synthesize oligonucleotides against all viruses. The specification has not taught, one of ordinary skill in the art, how to make oligonucleotides against each and every virus. Working examples have been provided for HSV, HIV, CMV, RSV, coxsackie B12, DHBV, parainfluenza 3 and Hanta virus. One of ordinary skill in the art would not be able to make oligonucleotides for other viruses. Undue experimentation would be necessary to synthesize oligonucleotides against every virus.

Claim Rejections - 35 USC § 102

Claims 52-56 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,013,639, Peyman et al. Claims 52-56 are drawn to a method for selecting an antiviral compound for use against a target virus different from HIV-1, HSV-2, HSV-2, CMV, RSV, parainfluenza virus and HBV comprising:

(A) Synthesizing a plurality of different oligonucleotides, wherein at least one of said oligonucleotides is at lest 10 nucleotides in length.
(B) Testing said oligonucleotides for activity in inhibiting the ability of said target virus to produce infectious virions.
(C) Selecting said oligonucleotide having a pharmaceutically acceptable level of activity for use as an anti-viral agent.
(D) Wherein said different oligonucleotides comprise:
(a) Randomers of different length.
(b) A set of oligonucleotides of different length, each oligonucleotide in said set comprising the sequence of the shortest oligonucleotide in said set.
(c) A plurality of oligonucleotides comprising a randomer of at least 6 nucleotides in length.
(d) Oligonucleotides are not complementary to any mRNA sequence of said target virus.

Peyman teaches methods for the preparation of modified oligonucleotides with phosphorothioate bridges and that these oligonucleotides can be linked to molecules (column 3, lines 25-35), which have a favorable influence on the properties of antisense oligonucleotides (column 4, lines 61-64). The oliginucleotides have a length from 6 to 60 nucleotides (column 6, lines 21-24). The invention teaches a process for preparing pharmaceutical compounds or therapeutically effective oligonucleotides (column 5, lines

26-31). The pharmaceuticals may be used for treating diseases, which are caused by viruses, for example, HIV, HSV-1, HSV-2, influenza, VSV, hepatitis B or papilloma viruses (column 6 lines 26-29).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 52-56 of this application conflict with claims 53-57 of Application No. 10/969,812. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 52-56 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 53-57 of copending Application No. 10/969,812. This

is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Housel James can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Hurt

February 27, 2006

JEFFREY STUCKER
PRIMARY EXAMINER